

# Lifestyle intervention and physical capacity in patients with morbid Obesity (LEICO)

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## **Background**

Physical inactivity provides reduce years of life, physical capacity, physical strength, quality of life, energy expenditure, sleep quality, appetite regulation, and increased degree of dysfunctional eating behavior (1, 2). Increased physical activity prevent overweight and help reduce weight (3, 4) and some studies have suggested that an increase in physical capacity of 8-21% can increase daily energy expenditure by 70-500 kilocalories, which may result in 1.5 to 10 kg weight reduction in one year (5, 6). Physical capacity may also be important for weight stabilization after weight loss (1, 7). A combination of physical activity and calorie reduction is therefore appropriate to decrease body weight (8). One of the few studies that mapped physical capacity after a lifestyle treatment found no significant change in body weight or physical capacity (9). However, the researchers found greatest weight loss in patients with the greatest progress in physical capacity. Anyway, it is not clear how physical activity and capacity affect the loss or maintenance of body weight in patients with morbid obesity.

In summary, it is still uncertainty about which is the most effective lifestyle treatment to reducing body weight and increased quality of life. Increased physical capacity and muscle mass lead to increased energy expenditure, thus explaining parts of the difference in weight loss achieved after lifestyle treatment. However, literature in this area is limited and need better documentation of how, and to what extent increased physical capacity can affect the effect of lifestyle treatment offered to patients in the health service.

### **Research questions**

We want to investigate whether patients with good physical capacity (maximal oxygen uptake) at start of treatment and / or after 12 weeks of intensive exercise, have a greater weight loss 1 year after start of treatment than patients with low physical capacity.

This issue will be illustrate by the following hypotheses:

- 1. Physical capacity before start of treatment is associated with weight loss at 12-weeks and 1-year follow-up (FU)
- 2. The mean twelve-week change in physical capacity is associated with weight loss at 1- year FU.

#### Data

Standard treatment at Vestfold Hospital Trust, the following data is obtained at baseline, 12-weeks and 1-year follow up: body weight, hip circumference, waist circumference, body composition, body mass index, height, age, sex and physical capacity (maximal oxygen uptake). In this study, we wish to use the collected data to research the hypotheses above.

Body weight and height will be measure with light clothing, without shoes. The BMI is calculate as the weight (kg) divided by the square height (m). The waist circumference (cm) will be measure midway between the lower edge of the lower rib and the upper part of the hip joint in the horizontal plane. Hips circumference (cm) will be measure on the widest part of the back in the horizontal plane. Body composition is analyzed using bioimpedance analysis (Tanita BC-418). Physical capacity will be measure as maximum oxygen uptake (VO2max) by indirect calorimetry (Jaeger Oxycon Pro). Indirect calorimetry is to be regard as a gold standard for measurement of maximum oxygen uptake.



The test will be conduct as an individual custom protocol with gradual increase of incline and / or speed on treadmill (Woodway®) up to voluntary maximum fatigue.

#### Informed consent

We want to send out information to 200 patients who have participated on a day-to-day intensive lifestyle treatment for morbid obesity at Vestfold Hospital Trust (from November 2013 to May 2016), they actively contact if they not want the above information to be used in the research project.

Data included in the project is already obtained in existing treatment program, and patients are not exposed to any deviations from the standard treatment at Vestfold Hospital Trust. Patients complete self-assessment forms for testing and exercise at the start of the treatment program. We want to emphasize that research will be conducted on unidentified data, and the results will not be linked to the individual patient. Patient information will be treated strictly confidential. Researchers will only use anonymized data.

# **Statistical methods**

Intention to treat analyses will be performed in order to compare the effects of the treatment. Differences in outcome measures between patients will be assessed using analysis of covariance (ANCOVA), including baseline value of the dependent variable as covariate. Simple and multiple logistic regression will be implement to assess the changes of variables.

#### Research group

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#### Kilder

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